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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,301	02/01/2002	Yusuke Nakamura	1254-0195P	7091

2292 7590 03/09/2005

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EXAMINER

KIM, YOUNG J

ART UNIT PAPER NUMBER

1637

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/060,301	Applicant(s) NAKAMURA ET AL.	
	Examiner Young J. Kim	Art Unit 1637	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 13 January 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-3 and 5.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 2/2/05
13. ☐ Other: _____.

Continuation of 5. Applicant's reply has overcome the following rejection(s): In view careful reconsideration and in view of Applicants' arguments received on January 13, 2005, the rejection of claims 1-5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description - New Matter Rejection - made in the Office Action mailed on February 4, 2005 is withdrawn.. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Wang et al. (Science, May 1998, vol. 280, pages 1077-1082), made in the Office Action mailed on July 14, 2004 is withdrawn in view of the Amendment, amending the claim to include the limitation of claim 4.

Continuation of 11. does NOT place the application in condition for allowance because: The rejection of claim 5 under 35 U.S.C. 102(b) as being anticipated by Wang et al. (Science, May 1998, vol. 280, pages 1077-1082) made in the Office Action mailed on July 14, 2004 is maintained for the reasons of record. Applicants' arguments received on January 13, 2005 have been fully considered but they are not found persuasive for the following reasons. Applicants' arguments are addressed in the same order they were presented. Applicants contend that Wang et al., while appearing to disclose multiplex PCR using a plurality of primers, the artisans employ an amount of DNA that, "falls outside the scope of the instant claims." (page 6, Response). Applicants state that artisans employ 100 ng of DNA for analysis of ~23, 46, or 93 loci (on page 6, bottom paragraph, Response), which would render the amount of DNA being employed fall outside of the claimed range, "by at least a factor of 5."

This argument is not found persuasive. According to the limitation found on claim 1, a range of 10-40 ng of DNA per 100 sites would equal to 0.1 ng to 0.4 ng per a single site. While Applicants have correctly cited that Wang et al. amplified ~23, 46, or 93 loci, Applicants apparently missed the 558 loci amplified as discussed in the Office Action mailed on July 14, 2004. Specifically, Wang et al. states: "[w]e developed a protocol based on multiplex PCR in which primer pairs from many different loci are combined in a single reaction...single set of 558 loci." (page 5 of the Office Action mailed on July 14, 2004 and page 1080, 3rd column of Wang et al.). 558 loci per 100 ng would be well within the claimed range, and therefore, Wang et al. properly anticipate the invention as claimed.

The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Walburger et al. (Mutation Research, January 2001, vol. 432, pages 69-78), made in the Office Action mailed on July 14, 2004 is maintained for the reasons of record. Preliminarily, the rejection of claim 4 is rendered moot in view of its cancellation in the Amendment received on January 13, 2005.

Applicants' arguments received on January 13, 2005 have been fully considered but they are not found persuasive for the following reasons.

Applicants contend that Walburger also requires use of much more DNA per assay than the range stated in the instant claims. It appears that there is disagreement in the claim interpretation.

The phrase controlling the disagreement is in claim 1 which recites the step: simultaneously amplifying a plurality of nucleotide sequences comprising at least ONE or more sites of single nucleotide polymorphism using genomic DNA whose amount is 10-40 nm per 100 sites and a plurality of primers.

Contrary to the Applicants' assertion, the method does not require that it detect 100 sites. All the method requires is that at least one polymorphism be detected, so long as the amount of DNA used in the method is proportional to the amount recited, "10-40 ng per 100 sites." In other words, the phrase would embrace a method of detecting a single polymorphism in a genomic DNA using 10 ng-40 ng of DNA so long as the genomic DNA harbored at least 100 polymorphic sites. The method does not require that 100 sites be detected nor do the claims require that at 100 primer sets be employed.

Additionally, Walburger et al. disclose that 9ng of genomic DNA is employed for the Light Cycler detection method (page 72, 1st column), contrary to Applicants' asserted "100 ng."

Therefore, the invention as claimed is anticipated by Walburger et al.

The rejection of claims 2 and 3 under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (Science, May 1998, vol. 280, pages 1077-1082) in view of Brookes (US 2001/0046670 A1, published November 29, 2001, priority October 7, 1999), made in the Office Action mailed on July 14, 2004 is maintained for the reasons of record.

Applicants' arguments received on January 13, 2005 have been fully considered but they are not found persuasive for the following reasons.

All of Applicants' arguments are drawn to the Wang reference, which, as discussed above, properly anticipate the claimed invention and therefore, the rejection is maintained.

The rejection of claim 3 under 35 U.S.C. 103(a) as being unpatentable over Walburger et al. (Mutation Research, January 2001, vol. 432, pages 69-78) in view of Wang et al. (Science, May 1998, vol. 280, pages 1077-1082), made in the Office Action mailed on July 14, 2004 is maintained for the reasons of record.

Applicants' arguments received on January 13, 2005 have been fully considered but they are not found persuasive for the following reasons.

All of Applicants' arguments are drawn to the references not teaching the claimed genomic DNA amount. However, as already discussed above, Wang et al. and Walburger et al. disclose this claimed range, and therefore, the rejection is maintained.

YOUNG J. KIM
PATENT EXAMINER

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

7/23/05

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EXAMINER

ART UNIT	PAPER
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